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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,791	02/27/2006	Yorimasa Suwa	1254-0305PUS1	6478

2292 7590 03/12/2009

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

NOTIFICATION DATE	DELIVERY MODE
03/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/569,791	SUWA ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008 and 22 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 23-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 23-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 12/22/08 and 11/21/08 has been entered.

Applicant's arguments filed 11/21/08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 23-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 9 and 23 have been amended. Applicant points to page 9 of the specification for basis. The claims are directed to a screening method for substances that have a mechanism of pharmacological action similar to that of pioglitazone by determining the presence or absence of

any interaction with SEQ ID NO: 2 and variants thereof. The generic screening methods now claimed were not disclosed nor contemplated by the originally filed specification. The whole disclosure of the specification is directed to finding compounds that interact with SEQ ID NO: 2 **and are antidiabetic substances**. Applicant is reminded that piaglitazone has uses in addition to applications in diabetes. For example, Hobbs et al. (U.S. Patent No. 7,034,056) discloses uses of pioglitazone in treating obesity. (See at least claim 26.) For example, Chandraratna et al. (U.S. Patent No. 7,105,566) discloses uses of pioglitazone in treating vascular trauma. (See at least claim 16.)

There is no disclosure of identifying substances having a mechanism of pharmacological action similar to that of pioglitazone that are not antidiabetic substances. There is no disclosure that SEQ ID NO: 2 or variants thereof bind to rosiglitazone, trolitazone or ciglitazone. There is no disclosure to bring a candidate compound into contact with a mutant of SEQ ID NO: 2 that interacts with rosiglitazone, trolitazone or ciglitazone.

Finally, determining that a candidate substance does or does not have an interaction with SEQ ID NO: 2 or a variant thereof does not establish that the candidate compound has a mechanism of action similar to that of pioglitazone as required by the preamble of the claims. These methods are not disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 23-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method steps of the claims do not provide the result of the preamble. Determining that a candidate substance does or does not have an interaction with SEQ ID NO: 2 or a variant thereof does not establish that the candidate compound has a mechanism of action similar to that of pioglitazone as required by the preamble of the claims. In addition, the claim does not make clear what pharmacological action of pioglitazone is intended and what level of similarity would meet the limitations of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 23-27, 32-33, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ota et al. (U.S. Patent Application Publication 20070105122 A1).

Ota et al. discloses SEQ ID NO: 12235 which is identical with instant SEQ ID NO: 2. (See alignment in prior Office action.) Ota et al. discloses screening assays of candidate compounds such as small molecules and proteins with the protein of SEQ ID NO: 12235. See at least abstract, claims, page 1189, and alignment below. The protein of SEQ ID NO: 12235

would inherently be capable of interacting with the thiazolidine derivative pioglitazone as it is identical to instant SEQ ID NO: 2. (See claims 9 and 32-33.) The candidate compounds are not disclosed as being antidiabetic agents. (See claims 40-41.)

The only steps required by the claimed method are bringing a candidate substance to be screened into contact with the protein of SEQ ID NO: 2 and screening for the presence or absence of any interaction between them. Ota et al. discloses these steps.

Claims 9, 23-33, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (U.S. Patent Application Publication 20070224201 A1).

Wu et al. discloses tumor-associated antigen target (TAT) polypeptide SEQ ID NO: 4169 which is identical with instant SEQ ID NO: 2. (See alignment in prior Office action.) Wu et al. discloses high throughput screening assays of candidate compounds such as small molecules and proteins with the protein of SEQ ID NO: 4169. The polypeptide being assayed can be immobilized on a microtiter plate. Any known assay techniques can be used. See at least abstract, claims, page 240-242, paragraphs [6695-96, 6702-6705], and alignment below. The protein of SEQ ID NO: 4169 would inherently be capable of interacting with the thiazolidine derivative pioglitazone as it is identical to instant SEQ ID NO: 2. (See claims 9 and 32-33.) The candidate compounds are not disclosed as being antidiabetic agents. (See claims 40-41.) With respect to claims 28-31, applicant's basis for these claims is Reference Example 1 and page 15. These disclosures are directed to the protein immobilized on a microtiter plate. As such, the teachings of Wu et al. are deemed to meet the limitation of these claims.

The only steps required by the claimed method are bringing a candidate substance to be screened into contact with the protein of SEQ ID NO: 2 and screening for the presence or absence of any interaction between them. Wu et al. discloses these steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of the specification at page 15.

This rejection is maintained for reasons of record.

The only steps required by the claimed method are bringing a candidate substance to be screened into contact with the protein of SEQ ID NO: 2 and screening for the presence or absence of any interaction between them. Wu et al. discloses these steps and discloses that any assay technique could have been used. Page 15 of the specification discloses that surface

plasmon resonance using platforms such as the Biacore 3000 would have been well known in the art at the time of the invention. As such, the methods of claims 34-35 would have been obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa